

**United States Court of Appeals
for the Federal Circuit**

REMBRANDT DIAGNOSTICS, LP,
Appellant

v.

ALERE, INC.,
Appellee

**KATHERINE K. VIDAL, UNDER SECRETARY OF
COMMERCE FOR INTELLECTUAL PROPERTY
AND DIRECTOR OF THE UNITED STATES
PATENT AND TRADEMARK OFFICE,**
Intervenor

2021-1796

Appeal from the United States Patent and Trademark
Office, Patent Trial and Appeal Board in No. IPR2016-
01502.

Decided: August 11, 2023

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Before MOORE, *Chief Judge*, DYK and REYNA, *Circuit Judges*.

REYNA, *Circuit Judge*.

This case returns to us from the Patent Trial and Appeal Board. Appellant Rembrandt appeals a final written decision in an *inter partes* review in which the Board found that claims 3–6 and 10 of U.S. Patent No. 6,548,019 would have been unpatentable for obviousness. Rembrandt argues that the Board erred by relying on Appellee Alere's new theories asserted for the first time in its reply brief. Because Alere did not offer new theories and because substantial evidence supports the Board's determinations, we affirm.

BACKGROUND

A. The '019 Patent

We provide a brief overview of U.S. Patent No. 6,548,019 (the "019 patent") because we previously discussed the patent in detail in *Alere, Inc. v. Rembrandt Diagnostics, LP*, 791 F. App'x 173 (Fed. Cir. 2019) and *Rembrandt Diagnostics, LP v. Alere, Inc.*, 809 F. App'x 903 (Fed. Cir. 2020). The '019 patent is directed to test assay devices and methods for testing biological fluids. '019 patent at 1:15–18. The test assay device receives a fluid sample "introduced directly to the sample loading zone" (30) of one or more assay test strips (22). *Id.* at 4:65–5:6; 7:54–62.

As shown in Figures 3 and 6 below, the assay test strips (22) may each be encapsulated within separate “flow control channel[s]” (34) in one embodiment. *Id.* at 1:39–47; 5:51–59; 6:46–47.

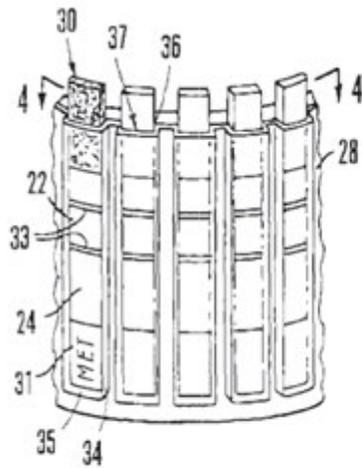


Fig. 3

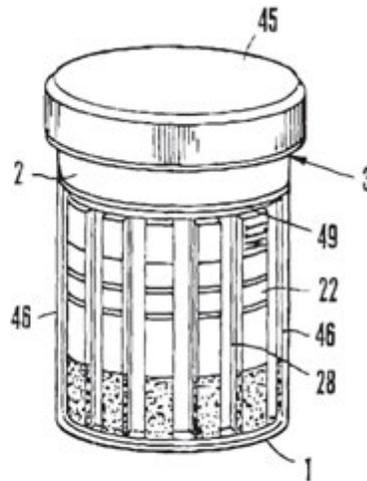


Fig. 6

Id. at Figs. 3 & 6. Figure 6 illustrates that to assemble the full testing assay device, the test strip assembly (22, 28, 34) from Figure 3 may be combined with a holder (40) and placed inside a fluid sample container (i.e., a cup) (2) that has a cap (45) to fit over the opening (3) of the container. *Id.* at 5:53–64; 6:15–45; 7:11–28; Figs. 5 & 6. Figure 6 also shows that the sample loading zones (30) of the assay test strips are oriented toward the base (1) of the fully assembled container. *Id.* at 6:35–45; 7:22–27. As the assay sample fluid in the container contacts the sample loading zone (30), it migrates upward through the assay test strip. *Id.* at 6:55–67. In another embodiment, multiple test strips may be held within a single “continuous in width” flow control channel. *Id.* at 6:47–54.

Claims 3–6 and 10 are the focus of this appeal. These claims all depend (either directly or indirectly) from claim 1, which is directed toward the assay testing device. Claims 1 and 9 were disclaimed by Rembrandt and are not at issue on appeal. J.A. 3. Claims 3–6 and 10 all include this arrangement of test strips “oriented toward” the base of the container. ’019 patent at 8:57–59; J.A. 75. Claim 10 is directed to the embodiment where “all of the assay test strips are disposed in a single flow control channel.” *Id.* at 10:5–6.

B. The Prior Art

Alere argued before the Board that the challenged claims would have been obvious over two combinations of prior art patents relating to assay testing devices: (1) U.S. Patent No. 5,656,502 (“MacKay”) in view of U.S. Patent No. 5,985,675 (“Charm”) or U.S. Patent No. 5,602,040 (“May”) and (2) U.S. Patent No. 6,379,620 (“Tydings”) in view of MacKay or U.S. Patent No. 5,500,375 (“Lee-Own”). J.A. 13, 25. We briefly summarize the relevant portions of these prior art patents.

Turning to the first combination, MacKay describes a test strip holder that holds one test strip. J.A. 1423 at 1:5–6. In MacKay, one end of the holder is open to allow liquid to enter so that the liquid can reach the sole test strip inside. J.A. 1424–25 at 3:10–18; 5:66–6:21; 6:55–58. Charm discloses that its “test device may employ one or more test strips directed to a variety of tests.” J.A. 1446 at 4:6–12. May explains that “a device according to the invention can incorporate two or more discrete bodies of porous solid phase material, e.g., separate strips or sheets, each carrying mobile and immobilised reagents.” J.A. 1526 at 6:26–29.

For the second combination, Tydings, which shares an inventor with the ’019 patent, discloses test strips that are oriented upwards toward the mouth of the container (the opposite of the ’019 patent’s configuration). J.A. 1477 at

2:46–67; Fig. 1. Tydings’s objectives include providing a testing device that is “simple to use and inexpensive and easy to manufacture.” J.A. 1477 at 1:40–42. Lee-Own’s test strip is placed inside a sealed “holder laminate” and advantageously does “not require extraneous wicks” “to augment sample migration.” J.A. 1467–69 at 3:26–34; 3:65–67; 7:28–39; 7:53–62. Lee-Own also explains “a single strip or multiple strips” may be included within the laminate structure to run multiple tests simultaneously. *Id.* at 1:42–44; 3:40–42; 5:1–12; 8:54–57.

PROCEDURAL HISTORY

This dispute began in 2016 when Rembrandt sued Alere in district court for patent infringement. The district court case is currently stayed pending the outcome of this appeal.

A. The Board Proceeding

After Rembrandt sued, Alere petitioned for *inter partes* review (“IPR”) before the Patent Trial and Appeal Board (“Board”) challenging claims 1–6 and 9–15 of the ’019 patent. J.A. 81–173. The IPR was based on, among other references, Tydings, MacKay, May, Lee-Own, and Charm. *Id.* The Board instituted only on certain grounds and declined to review claims 6 and 10. J.A. 302–38. In declining to review claim 10, based on MacKay in view of Charm or May, the Board explained that Alere did not sufficiently explain how MacKay’s device would be modified. J.A. 332–33. After institution, Rembrandt disclaimed claims 1, 9, and 11–15, leaving claims 2–5 for the Board to review. J.A. 3. The Board issued a final written decision in February 2018, finding that while claim 2 was anticipated by MacKay, Alere had failed to prove claims 3–5 were unpatentable. *See Alere Inc. v. Rembrandt Diagnostics, LP*,

No. IPR2016-01502, 2018 WL 852133, at *11 (P.T.A.B. Feb. 9, 2018).

Alere appealed. *See Alere, Inc.*, 791 F. App'x at 174. It challenged the Board's determination as to claims 3–5, the Board's claim construction of a disputed term, and asked this court to remand for the Board to consider all non-instituted claims and grounds under the Supreme Court's decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018). *Id.* at 176, 178. We affirmed the Board's claim construction but remanded for the Board to consider all the challenged claims and grounds under *SAS*. *Id.* at 178.

B. Remand Proceeding

On remand from this court, the Board authorized “briefing with respect to all non-instituted grounds set forth in the [p]etition.” J.A. 692–94. Rembrandt filed a patent owner response addressing those grounds but did not submit an accompanying expert declaration. J.A. 697–740. Alere filed a reply with an accompanying declaration from its expert, Dr. Robert Bohannon, responding both to Rembrandt's arguments and to the observations the Board raised in its original institution decision. J.A. 743–79; J.A. 1891–1933 (¶¶ 38–51, 68–74). Rembrandt's sur-reply followed. J.A. 788–813.

On sur-reply, Rembrandt argued that Alere “resort[ed] to new theories in reply.” J.A. 793. Regarding a ground not at issue here—MacKay and Cipkowski—Rembrandt argued that Alere and Dr. Bohannon “propose[d] three new theories” in reply and that the Board should thus “disregard[]” them. J.A. 794–95, 801–05. Rembrandt, however, did not specifically contest that Alere or Dr. Bohannon raised new theories in reply for the two combinations at issue here: (1) MacKay in view of Charm or May, and (2) Tydings in view of MacKay or Lee-Own. J.A. 806–13. At the oral hearing before the Board, Rembrandt repeated that Alere allegedly offered “new evidence and arguments”

and discussed MacKay and Cipkowski as an example. J.A. 974–75.

In February 2021, the Board issued its post-remand final written decision finding claims 2–6 and 10 unpatentable. *See Alere Inc. v. Rembrandt Diagnostics, LP*, No. IPR2016-01502, 2021 WL 471532, at *25 (P.T.A.B. Feb. 9, 2021) (“*Decision*”); J.A. 1–65.¹ For claims 3–6, the Board found that Tydings, MacKay, and Lee-Own demonstrate these claims would have been obvious because Alere relied “on credible expert testimony [by Dr. Bohannon] and documentary evidence” on why a skilled artisan would modify Tydings “to remove the wicking material and re-orient the flow control channels towards the bottom of the container.” *Decision*, at *14. The Board rejected Rembrandt’s arguments that wicking material was “fundamental” to Tydings, *id.* at *13, and credited Dr. Bohannon’s un rebutted testimony that eliminating the wicking material would reduce cost, complexity, and oversaturation of the test strip, *id.* at *11–14. The Board also relied on Dr. Bohannon’s testimony that Lee-Own’s disclosure expressly supplies a motivation to combine because it lists no need for “extraneous wicks” as one of the “advantage[s]” of its invention. *Id.* at *13.

As for claim 10, the Board found it would have been obvious over MacKay in view of Charm or May. *Id.* at *10. The Board found that, although MacKay teaches a single test strip, Dr. Bohannon’s un rebutted testimony supported that a skilled artisan would have modified MacKay based on Charm and May’s teachings that it was advantageous to use multiple test strips with a single device. *Id.* at *9. The Board determined that a skilled artisan would have understood “the multiple test strips of Charm and May are

¹ Rembrandt has not challenged on appeal the Board’s finding that MacKay anticipates claim 2. *Decision*, at *2, *25 n.19.

located within a single flow control channel.” *Id.* at *8, *9 n.14. Accordingly, the Board concluded that a skilled artisan would have found it obvious to “successfully dispose multiple test strips in the single flow control channel of MacKay” because doing so “would be more efficient and use less resources than a device with multiple flow control channels.” *Id.* at *8. Rembrandt petitioned for Director rehearing, which was denied. J.A. 2366–68.

Rembrandt appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

LEGAL STANDARD

“Decisions related to compliance with the Board’s procedures are reviewed for an abuse of discretion.” *Ericsson Inc. v. Intel. Ventures I LLC*, 901 F.3d 1374, 1379 (Fed. Cir. 2018). “An abuse of discretion is found if the decision: (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact finding; or (4) involves a record that contains no evidence on which the Board could rationally base its decision.” *Id.* (citation omitted).

We review the Board’s legal conclusion on obviousness *de novo* and its underlying factual findings for substantial evidence. *Id.* The underlying factual findings include the “scope and content of the prior art,” the “differences between the prior art and the claimed invention,” and “the presence or absence of a motivation to combine.” *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1364 (Fed. Cir. 2015).

DISCUSSION

Rembrandt argues that the Board abused its discretion when it relied on Alere’s new theories and evidence, and alternatively, that substantial evidence fails to support the Board’s unpatentability determinations. Alere disagrees with both arguments. Alere asserts that Rembrandt forfeited the new theories and evidence argument, but even if

not forfeited, that Rembrandt's position lacks merit because Alere's theories and evidence were responsive to Rembrandt's arguments and the Board's observations. Alere also contends that substantial evidence, including un rebutted expert testimony, supports the Board's factual findings. We address each issue in turn.

I.

We hold that the Board did not abuse its discretion by relying on Alere's theories and evidence. *First*, we agree with Alere that Rembrandt forfeited its argument that Alere offered new theories. Forfeiture is the failure to make the timely assertion of a right. *See Philip Morris Prods. S.A. v. Int'l Trade Cmm'n*, 63 F.4th 1328, 1336 (Fed. Cir. 2023). Alere contends that Rembrandt forfeited its new-theories argument by expressly objecting to one obviousness ground (MacKay in view of Cipkowski) for allegedly raising new theories without also making the same objection to the grounds at issue here (MacKay in view of Charm or May; and Tydings in view of MacKay or Lee-Own). Rembrandt contends that it objected to the grounds here on the first page of its brief where it stated that Alere "resorts to new theories in reply," J.A. 793, and at the oral hearing before the Board, J.A. 974–75.

We hold that Rembrandt's generic objection is insufficient to constitute a proper objection—especially because Rembrandt expressly objected to other allegedly new theories without doing so here. *Compare* J.A. 794–95; J.A. 801–05; J.A. 974–75, *with* J.A. 806–13. Indeed, it would be unfair to both the parties and the Board to read so broadly such a generic objection: Neither would have adequate notice of which theories are allegedly new. This would be particularly problematic for the Board, as it must "make judgments about . . . when a [r]epley contention crosses the line from the responsive to the new." *Ariosa*, 805 F.3d at 1368.

Second, we address Rembrandt’s new-theories argument. The petitioner in an IPR must “identify ‘with particularity’ the ‘evidence that supports the grounds for the challenge to each claim.’” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (quoting 35 U.S.C. § 312(a)(3)); *see also* 37 C.F.R. § 42.22(a). Following institution, the patent owner may submit a response with supporting factual evidence and expert opinions. *See* 35 U.S.C. § 316(a)(8); 37 C.F.R. § 42.120. In reply, the petitioner may “only respond to arguments raised in the corresponding opposition, patent owner preliminary response, patent owner response, or decision on institution.” 37 C.F.R. § 42.23(b). And in sur-reply, the patent owner “may only respond to arguments raised in the corresponding reply and may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness.” *Id.*

We have held that in some circumstances the Board acts within its discretion when declining to consider a new theory of unpatentability raised by petitioner in reply or a new theory of patentability raised by patent owner in sur-reply. In *Intelligent Bio-Systems*, for instance, the petitioner asserted in its petition that a single reference disclosed a limitation and then instead argued in its reply that there was a motivation to combine references to arrive at that limitation. 821 F.3d at 1369. We concluded that petitioner’s motivation-to-combine argument was an impermissible “new theory of invalidity” and affirmed the Board’s decision to exclude the reply and accompanying evidence. *Id.* at 1369–70; *see also* *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1329–31 (Fed. Cir. 2019) (rejecting a new theory of unpatentability where petitioner argued for the first time in its reply that a reference disclosed a limitation); *Wasica Fin. GmbH v. Cont’l Auto. Sys., Inc.*, 853 F.3d 1272, 1286 (Fed. Cir. 2017) (finding that petitioner’s “subsequent arguments amount to an entirely

new theory of *prima facie* obviousness absent from the petition”).

And in *Ariosa*, for example, we held that a petitioner who asserted in its reply previously unidentified prior-art disclosures “to make a meaningfully distinct contention” was impermissibly raising a new theory of unpatentability. 805 F.3d at 1367. There, the petitioner generically argued in the petition that any method could be used to perform a particular sequencing step without discussing how the type of method may impact the use of a certain primer. *Id.* In reply, the petitioner attempted to address counterarguments of incompatibility of the references by switching theories to argue that some embodiments do not use that specific primer, citing previously unidentified embodiments of the reference. *Id.* at 1367–68. We affirmed the Board’s rejection of this new theory. *Id.* at 1368.

In other circumstances, we have held that a reply may be proper if it is responsive and simply expands on previously raised arguments. For example, in *Ericsson*, we reversed the Board’s decision to exclude the petitioner’s reply argument in part because the petitioner had “merely expand[ed] on a previously argued rationale as to why the prior art disclosures are insubstantially distinct from the challenged claims.” 901 F.3d at 1381. We cautioned the Board not to parse “arguments on reply with too fine of a filter.” *Id.* at 1380; *see also Chamberlain Grp., Inc. v. One World Techs., Inc.*, 944 F.3d 919, 925 (Fed. Cir. 2019) (“Parties are not barred from elaborating on their arguments on issues previously raised.”); *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1081–82 (Fed. Cir. 2015) (reasoning that rebuttal evidence should be responsive such that it is offered “to explain, repel, counteract, or disprove the evidence of the adverse party”).

And in *Apple Inc. v. Andrea Electronics Corp.*, we found that the Board abused its discretion in excluding “another example” of the same prior-art reference’s algorithm used

in both the petition and reply to “further explain” its legal argument. 949 F.3d 697, 706 (Fed. Cir. 2020). We concluded that the petitioner’s reply asserted the same “legal ground” as its petition because it relied on the “same prior art” to support the “same legal argument.” *Id.* (explaining that “responsive” arguments “eliminate[]” “any ambiguity” of a new argument). Thus, the very nature of the reply and sur-reply briefs are to respond (whether to refute, rebut, explain, discredit, and so on) to prior raised arguments within the confines of 37 C.F.R. § 42.23(b).

Since the need to rely on new evidence in response may not arise until a particular point has been raised in the patent owner response or the institution decision, we have held that there is no blanket prohibition against the introduction of new evidence during an IPR. *See Anacor Pharms., Inc. v. Iancu*, 889 F.3d 1372, 1380–82 (Fed. Cir. 2018) (explaining that the petitioner “may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner”). In fact, “the introduction of new evidence in the course of the trial is to be expected in [IPR] trial proceedings” and permissible “as long as the opposing party is given notice of the evidence and an opportunity to respond to it.” *Genzyme Therapeutic Prods. Ltd. P’ship v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1366 (Fed. Cir. 2016).

With these principles in mind, we turn to whether Alere’s reply arguments were improper. Rembrandt argues Alere raised several new theories. We need only discuss two representative examples.

We start with claim 10. Rembrandt contends that Alere improperly raised the benefit of cost and time savings as a new argument in reply to modify MacKay. Alere had asserted in its petition that modifying MacKay to hold multiple test strips in a single housing, as taught by Charm and May, would have increased the “efficiency” of MacKay by allowing “multiple tests to be conducted

simultaneously.” J.A. 120. Rembrandt countered in its patent owner response that Charm and May did not “provide the missing motivation or expectation of success” to accommodate additional test strips. J.A. 725. Alere argued, in its reply, that a skilled artisan would understand “additional strips would save cost and time by allowing for rapid, efficient, simultaneous testing for multiple analytes,” which can be successfully accommodated by MacKay’s structure. J.A. 768 (citing J.A. 1918–19, ¶ 47).

Alere’s reply argument discussing cost and time savings has a nexus to Rembrandt’s prior argument and is responsive. It refutes Rembrandt’s assertions that there is no motivation to add multiple test strips or an expectation of success. And by discussing time and cost savings as a form of efficiency, it also properly expands on and is a fair extension of its previously raised efficiency argument. *See Ericsson*, 901 F.3d at 1381.

Rembrandt’s arguments for claims 3–6 fare no better. Rembrandt contends, for instance, that Alere improperly raised the benefits of reducing cost and simplifying a device as a new argument in reply to modify Tydings. Alere had argued in its petition that it would have been obvious to dispense with Tydings’s wicking material to “achieve the benefits of having the liquid sample contact the test strip only [at] a predetermined designated area designed for direct contact with the liquid as taught by MacKay or Lee-Own.” J.A. 163 (citing J.A. 1406, ¶ 190). In the original institution decision, the Board found that the petition did “not explain sufficiently why modifying Tydings to remove the wicking material would have been understood to be beneficial.” J.A. 336–37. Following this court’s remand, Rembrandt contended, in its patent owner response, that there was a lack of motivation to combine because Tydings’s use of an intermediate wicking material is fundamental to its invention. J.A. 736–37. Alere then argued, in its reply, that a skilled artisan would have been motivated to make the proposed modification of removing the

wicking material because it would align with Tydings’s objectives of “reduc[ing] cost” and “simplify[ing]” its device. J.A. 777 (citing J.A. 1929–30, ¶ 70). Alere cited previously unidentified disclosures of MacKay and Lee-Own for teaching the benefits of removing wicking material. *Id.*

We conclude that Alere’s reply argument is responsive to Rembrandt’s arguments and the Board’s observations. Alere disputes Rembrandt’s contention that wicking material is fundamental to Tydings and explains that removing wicking material would further achieve Tydings’s goals of inexpensive and easy manufacturing. J.A. 777. And Alere’s reply argument elaborates on the motivation-to-combine argument that Alere made in its petition—that there were benefits known in the art of removing the wicking material—by relying on MacKay and Lee-Own. *See Ericsson*, 901 F.3d at 1381.

Rembrandt next argues that Alere’s use of previously unidentified disclosures of MacKay and Lee-Own is impermissible, as were such disclosures relied on in *Ariosa*. 805 F.3d at 1367–68. We disagree. As we recognized in *Apple*, 949 F.3d at 706, the petitioner in *Ariosa* relied on “an embodiment of the prior art that was not discussed in the petition” to switch theories between its petition and reply. Unlike the petitioner there, Alere does not point to any new embodiments not previously identified to advance a meaningfully distinct contention from what it first asserted in its petition. It points to those additional portions to convey the benefits of removing wicking material as “a legitimate reply” to Rembrandt’s arguments and the Board’s observations. *Apple*, 949 F.3d at 706–07. Alere’s reply argument involves the same “legal ground” based on “the same prior art reference[s]” and the “same legal argument”—the motivation to remove Tydings’s wicking material and reverse its orientation. *Id.* at 706.

In short, Alere's responsive reply arguments do not constitute new theories, and the Board did not abuse its discretion in considering them.

II.

Rembrandt argues that the Board's factual findings underlying its obviousness determinations are not supported by substantial evidence. We disagree.

For MacKay in view of Charm or May, Rembrandt asserts that the references' disclosures fail to support the Board's finding that MacKay, Charm, or May accommodate multiple test strips. For example, Rembrandt contends that Charm's description of "the test device may employ one or more test strips directed to a variety of tests" only teaches the use of different types of test strips and does not teach using multiple test strips at the same time. Rembrandt makes a similar argument for May's description of "a device" with "separate strips." As for Tydings in view of MacKay or Lee-Own, Rembrandt argues that there is insufficient evidentiary support for the Board's finding that a skilled artisan would have been motivated to remove Tydings's wicking material and to reverse its orientation.

These arguments center on the interpretation of disclosures from the prior art and the presence of motivation to combine. But Rembrandt, as the Board explained, "cites to no counter testimony from a qualified declarant to refute Dr. Bohannon's conclusions regarding how [a skilled artisan] would have interpreted the identified disclosures." *Decision*, at *9 n.14 (noting Dr. Bohannon's testimony as "credible"). Based on our review of the record—particularly the express disclosure in the prior art and Dr. Bohannon's credible testimony—there is evidence that "a reasonable mind might accept" "as adequate to support" the Board's factual findings. *Henny Penny*, 938 F.3d at 1330. The Board was presented with "two alternative theories" about what the prior art discloses, and it is not this court's task "to determine which theory we find more compelling."

Shoes by Firebug LLC v. Stride Rite Childs. Grp., LLC, 962 F.3d 1362, 1371 (Fed. Cir. 2020). We hold that the Board's obviousness determinations are supported by substantial evidence.

CONCLUSION

The Board did not abuse its discretion when it relied on Aleré's responsive theories, and substantial evidence supports the Board's underlying factual findings. We therefore affirm the Board's determinations that claims 3–6 and 10 of the '019 patent would have been unpatentable due to obviousness. We have considered Rembrandt's other arguments and find them unpersuasive.

AFFIRMED

COSTS

No costs.